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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,846	08/02/2000	James D. Thompson	030206.0179.CON1	8327

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EXAMINER

LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/15/2003

9/15/19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/630,846

Applicant(s)

THOMPSON, JAMES D.

Examiner

Karen A. Lacourciere

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-19,21,24 and 25 is/are rejected.
- 7) ☒ Claim(s) 3-8,20,22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08-29-2002 has been entered.

***Claim Rejections - 35 USC § 112***

The rejection of record under 35 U.S.C. 112, first paragraph, has been withdrawn in response to Applicant's amendments filed 02-22-02.

***Claim Rejections - 35 USC § 102***

The rejection of record under 102(b) as anticipated by Inouye is withdrawn in response to Applicant's amendments submitted 08-29-2002.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an

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international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 9-19, 21, 24 and 25 are maintained as rejected under 35 U.S.C. 102(e) as being anticipated by Noonberg et al. (US Patent No. 5,624,803).

Noonberg et al. disclose RNA polymerase based constructs for generating oligonucleotides wherein the construct comprises a U6 RNA polymerase III promoter, and a region comprising a desired RNA and wherein the RNA comprises a region of complementarity between a 5' region and a 3' region (intramolecular stem region) which is generally between about 8 and about 30 nucleotides in length (see for example col 15, lines 45-50). Noonberg et al. specifically discloses their constructs wherein the construct comprises a region which transcribes a 5' lariat tail and a region which transcribes a 3' lariat tail, wherein the 5' tail and 3' tail flanking the desired RNA portion, such that transcription produces an RNA wherein the 5' tail and the 3' tail form a stable lariat structure by Watson Crick base pairing (see for example, column 15 line 58 to column 16, line 15). These lariat regions are complementary and, therefore,

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would be expected to base pair within the transcribed RNA molecule and, therefore, meet the limitations of the claimed compositions. Additionally, Noonberge discloses their oligonucleotide generators wherein the oligonucleotide has both stability and accessibility by building "a 5' and 3' self-complementary hairpin, creating a lariat-like structure with the oligonucleotide within the loop"(see for example column 18, lines 50 to 53). The RNA disclosed by Noonberg et al. includes an RNA that comprises an antisense oligonucleotide, a ribozyme, a triplex-forming molecule or combination (see for example col 14, lines 60-64). The RNA disclosed by Noonberg et al. is transfected into cells (see for example col 23, lines 35-67). Therefore, Noonberg et al. anticipates claims 1, 2, 9-19, 21, 24 and 25.

### ***Response to Arguments***

Applicant's arguments filed 08-29-2002 have been fully considered but they are not persuasive.

Applicant argues that the oligonucleotides generators disclosed by Noonberg et al. do not meet all of the limitations of the claims because the oligonucleotides disclosed by Noonberg et al. do not have 5' and 3' ends that form an intramolecular stem. Applicant points to figure 2 of Noonberg et al. to support that the structure of molecules disclosed by Noonberg et al. comprises intramolecular hairpins at each end of the molecule, rather than complementary 3' and 5' ends, as claimed.

These arguments have been considered, but are not found to be persuasive because figure 2 of Noonberg et al. illustrates one embodiment of

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their disclosed invention. Within the specification, Noonberg et al. describes structure comprising an intramolecular stem between the 5' and 3' terminus, with the desired RNA in the loop region. For example, Noonberg et al. specifically discloses their constructs wherein the construct comprises a region which transcribes a 5' lariat tail and a region which transcribes a 3' lariat tail, wherein the 5' tail and 3' tail flanking the desired RNA portion, such that transcription produces an RNA wherein the 5' tail and the 3' tail form a stable lariat structure by Watson Crick base pairing (see for example, column 15 line 58 to column 16, line 15). These lariat regions are complementary and, therefore, would be expected to base pair within the transcribed RNA molecule and, therefore, meet the limitations of the claimed compositions. Additionally, Noonberge discloses their oligonucleotide generators wherein the oligonucleotide has both stability and accessibility by building "a 5' and 3' self-complementary hairpin, creating a lariat-like structure with the oligonucleotide within the loop"(see for example column 18, lines 50 to 53). Therefore, Noonberg meets all of the limitations of the claimed invention.

### ***Claim Objections***

Claims 3-8, 20, 22 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere  
January 13, 2003